

IN THE SPECIFICATION:

Please amend paragraph [0011] as follows:

[0011] The sustained delivery of drugs has many advantages. Use of implantable devices assures patient compliance, since the delivery device ~~is tamperproof.~~ is tamperproof. With one insertion of a device, rather than daily injections, there is reduced site irritation, fewer occupational hazards for practitioners, improved cost effectiveness through decreased costs of equipment for repeated injections, reduced hazards of waste disposal, and enhanced efficacy through controlled release as compared with depot injection. The use of implantable devices for sustained delivery of a wide variety of drugs or other beneficial agents is well known in the art. Typical devices are described, for example, in U.S. Patent Nos.: 5,034,229; 5,057,318; 5,110,596; and 5,782,396. The disclosure of each of these patents is incorporated herein by reference.

Please amend paragraph [0024] as follows:

[0024] Figure 1 shows the stability of human growth ~~hormone~~ hormone (hGH) formulations of the present invention as determined at 37°C by reverse phase HPLC.

Please amend paragraph [0026] as follows:

[0026] Figure 3 shows the average release rate ~~( $\mu$ l/day)~~ ( $\mu$ g/day) of 10% (w/w) spray-dried lysozyme in formulations of the present invention.

Please amend paragraph [0027] as follows:

[0027] Figure 4 shows the average release rate ~~( $\mu$ l/day)~~ ( $\mu$ g/day) of 10% (w/w) spray-dried hGH in a glycerol monolaurate/lauryl lactate/polyvinylpyrrolidone vehicle.

Please amend paragraph [0052] as follows:

[0052] Generally, stable nonaqueous single-phase biocompatible viscous vehicles may be prepared by combining the dry (low moisture content) ingredients in a dry box or under other

dry conditions and blending them at elevated temperature, preferably about ~~40~~ 40°C to about 70°C, to allow them to ~~liquify~~ liquefy. The liquid vehicle is allowed to cool to room temperature. Differential scanning calorimetry was used to verify that the vehicle was single phase. The final moisture content of the viscous vehicle was <2%.

Please amend paragraph [0053] as follows:

[0053] Generally, the stable formulations of the present invention may be prepared by combining the vehicle and beneficial agent under dry conditions and blending them under vacuum at elevated temperature, preferably about ~~40~~ 40°C to about 70°C, to disperse the beneficial agent uniformly throughout the vehicle. The formulation is allowed to cool to room temperature.

Please amend paragraph [0056] as follows:

[0056] We have found that stable nonaqueous beneficial agent formulations utilizing viscous vehicles may be prepared by combining the ingredients for the viscous vehicle under dry conditions and blending them at elevated temperature to allow them to ~~liquify~~ liquefy and form a single phase. Once a single-phase viscous vehicle is formed, the vehicle is allowed to cool to room temperature. A beneficial agent is added by mixing at elevated temperature under vacuum to uniformly disperse it in the viscous vehicle.

Please amend paragraph [0064] as follows:

[0064] We have found that stable single-phase biocompatible viscous vehicles may be prepared by combining the ingredients and blending them at elevated temperatures to allow them to ~~liquify~~ liquefy and form a single phase. A differential scanning calorimetry scan showed one peak, indicative of a single phase. The mixing was completed under vacuum to remove trapped air bubbles produced from the powders. The mixer was a dual helix blade mixer (D.I.T.) which runs at a speed around 40 rpm. Higher speeds can be used but are not required.

Please amend paragraph [0065] as follows:

[0065] If a three-component viscous vehicle was prepared, the solvent portion of the vehicle was added to the heated bowl of the mixer first, followed by the surfactant. The polymer was added last, and the ingredients were mixed until a solution (single-phase) resulted. Vacuum was applied during mixing to remove air bubbles. The solution was dispensed from the bowl while at elevated temperature and allowed to cool to room temperature. On cooling, the vehicle exhibited increased viscosity. ~~Two and~~ Two- and single-component gels were made using the same process.

Please amend paragraph [0070] as follows:

[0070]

TABLE 1

RP-HPLC CHROMATOGRAPHIC CONDITIONS

Description	Parameter																		
Column	J.T. Baker-C18, 4.6x250 mm																		
Flow Rate	1.0 <del>mL/min</del> <u>mL/min.</u>																		
Detection	214 nm																		
Mobile Phase	A: 0.1% TFA in water B: 0.1% TFA in acetonitrile																		
Gradient	<table><tr><th><u>time</u></th><th><u>%A</u></th><th><u>%B</u></th></tr><tr><td>0</td><td>65</td><td>35</td></tr><tr><td>5</td><td>50</td><td>50</td></tr><tr><td>45</td><td>35</td><td>65</td></tr><tr><td>50</td><td>30</td><td>70</td></tr><tr><td>55</td><td>65</td><td>35</td></tr></table>	<u>time</u>	<u>%A</u>	<u>%B</u>	0	65	35	5	50	50	45	35	65	50	30	70	55	65	35
<u>time</u>	<u>%A</u>	<u>%B</u>																	
0	65	35																	
5	50	50																	
45	35	65																	
50	30	70																	
55	65	35																	

Please amend paragraph [0080] as follows:

[0080] D. Polyvinylpyrrolidone C17 (BASF, Mount Olive, NJ) (50 g) was dissolved in polyethylene glycol 400 (Union Carbide) ~~(50 g)~~ (50 g) at approximately 65°C until a

single-phase solution was formed. The single-phase vehicle was dispensed from the mixer and allowed to cool to room temperature.

Please amend paragraph [0087] as follows:

[0087]

TABLE 3

COMPONENT RATIOS

Polymer	Component Surfactant	Solvent	Ratio	Viscosity at Low Shear Rate (Poise)
PVP	GML	LL	53:5:42	25,000
PVP	GML	LL	55:10:35	50,000
PVP	GML	LL	50:15:35	7,000
PVP	-----	LA	60:40	
PVP	Ceraphyl 50	LA	60:10:30	
PVP	-----	oleic acid	50:50	30,000
PVP	-----	octanoic acid	55:45	7,000
PVP	polysorbate 80	-----	50:50	
PVP	-----	PEG 400	50:50	
PVP	<del>easter</del> <u>castor oil</u>	-----	50:50	
-----	Pluronic 105	-----	100	1,000,000
PVP	-----	glycerin	50:50	5,000

Please amend paragraph [0089] as follows:

[0089] Lyophilized hGH (BresaGen Limited, Adelaide, Australia) was reconstituted in 150 ml of deionized water. This stock solution contained 1050 mg of hGH. Buffer exchange was accomplished using an Amicon Diaflo® Ultrafiltration membrane (molecular weight cut-off 10,000). The ultrafiltration cell was connected to an auxiliary reservoir containing ~~5/mM~~ 5 mM phosphate buffer (pH 7). The cell's fluid volume, as well as the hGH concentration, remained constant as excipients were replaced by phosphate buffer.

Please amend paragraph [0094] as follows:

[0094] Approximately 10 mg of the spray-dried hGH powder were weighed out (content of hGH in the powder was recalculated based on the determined water and salt content) and mixed with 100  $\mu$ l of the vehicle at 55-65°C-(3- three samples per each vehicle). Special care was taken while mixing powder in the suspending vehicle to achieve maximum uniform particle dispersion in the vehicle. All steps were done in a dry box.